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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,702	06/01/2001	Eugen Koren	11669.72USU1	9131

23552 7590 07/10/2002

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EXAMINER

SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/10/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.



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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire ONE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-34 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-34 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☒ The specification is objected to by the Examiner. - Sequence Compliance
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Part III: Detailed Office Action

Sequence Compliance:

37 C.F.R. §1.821(d) reads as follows:

5 (d) Where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

10 The claims and/or specification are not in full compliance with 37 C.F.R. §1.821(d), and should be amended to refer to the appropriate sequence identifier(s) (SEQ ID NO:). For example, see claims 24-27. Correction is required.

Restriction Requirement:

15 Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, 22, 30 and 31, drawn to a method of modifying a polypeptide using antibody binding, classified in class 435, subclass 7.1.
- II. Claims 14-21, drawn to a method of modifying a polypeptide using an algorithm, classified in class 702, subclass 19.
- 20 III. Claims 23-34, drawn to a modified protein, nucleic acids encoding such, and method of treatment, classified in class 424, subclass 85.1, for example.

The inventions are distinct, each from the other because:

25 The modified proteins of Invention III are related to each of the methods of Inventions I and II because each of the methods might identify the protein. However, the Inventions are nonetheless distinct, because the modified protein is not dependent upon the method of production or identification of such, and could be arrived at via other, patentably distinct processes, such as random mutagenesis.

Inventions I and II are separate and distinct because although they have the same overall goal,

the method steps are substantively different, and require separate searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5

Election of Species Requirements:

1) In the event that applicants elect either Invention I or Invention III, further election of species is required:

10

This application contains claims directed to the following patentably distinct species of the claimed invention: modification by deletion, N-glycosylation, pegylation, substitution, and insertion. Each of these techniques is distinct and requires a separate search of the prior art. It is noted that deletion, substitution and insertion are all forms of mutation.

15

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-5, 9-13, 22, 23, and 30-33 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

20

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

25

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a

rejection under 35 U.S.C. 103(a) of the other invention.

2) In the event that applicants elect Invention I, a further election of species is required:

5 This application contains claims directed to the following patentably distinct species of the claimed invention: (a)thrombopoietin or cytokines, (b)growth hormones, (c) receptors, and (d) humanized antibodies. Note that TPO is considered to be a cytokine. Each of the four species requires a separate search and consideration of the prior art, as each constitutes a distinct group of proteins.

10 Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 5-13, 22, 30 and 31 are generic.

15 Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

20 Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

25 Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3) In the event that Invention III is elected, a further election of species is required:

This application contains claims directed to the following patentably distinct species of the

claimed invention: TPO comprising amino acids 1-311 of Figure 7, TPO comprising amino acids 1-317 of Figure 7, and TPO with at least one modification of amino acids 312-332 or 318-332. Each separate modification of TPO requires separate search and consideration for determination of obviousness over the prior art.

5 Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 23, 28-31 and 33 are generic.

 Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,
10 including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

 Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election,
15 applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

 Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a
20 rejection under 35 U.S.C. 103(a) of the other invention.

 Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any
25 amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Advisory Information:

To be fully responsive to this Office Action, applicants must elect one of Inventions I-III, and additionally indicate all applicable species elections, including a listing of claims readable upon the ultimate elected species. In addition, applicants are required to put the application in full compliance with 37 C.F.R. § 1.821(d). Failure to do so will result in the response being found non-responsive.

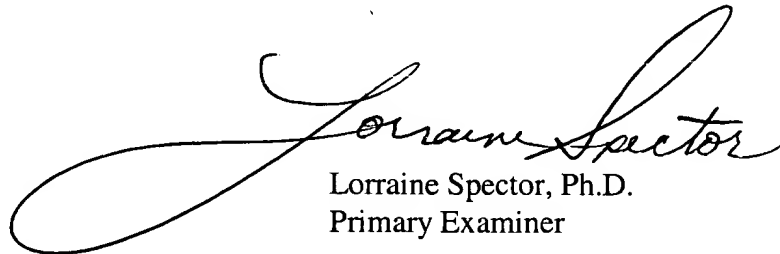
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.


Lorraine Spector, Ph.D.
Primary Examiner

LMS
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7/9/02